UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

WILLIE SEALS,	)	
	)	
Plaintiff(s),	)	
	)	
v.	)	Case No. 4:20-cv-01656-SRC
	)	
WRIGHT MEDICAL TECHNOLOGIES, INC.,	)	
	)	
Defendant(s).	)	

Memorandum and Order

Willie Seals had his left hip replaced with a Wright Medical hip implant. Seals later encountered complications requiring surgery, this time to replace the first implant with another. Seals claims that Wright Medical's metal-on-metal hip implant caused him severe injuries; Wright Medical claims that the FDA approved its at-the-time "state of the art" hip implants, and that Seals's doctor was aware of the risks and benefits of metal-on-metal implants when he selected it. As with most product-liability claims, the parties hired experts to provide various testimony. In this order, the Court considers Wright Medical's [60] [62] [64] motions to exclude Seals's experts, Seals's [59] motion to exclude Wright Medical's experts, and Wright Medical's [66] motion for summary judgment.

I. Uncontroverted material facts

In addressing the parties' Rule 702 motions below, the Court mentions the applicable facts as proffered by the parties. The Court finds the following facts undisputed for purposes of summary judgment.

Seals began experiencing pain in his left hip after breaking his pelvis and developing post-traumatic arthritis due to the fracture. Doc. 78 at ¶ 6. Seals went to an orthopedic surgeon,

Dr. Robert Barrack, for evaluation. *Id.* Dr. Barrack recommended a total left-hip replacement, and Seals elected to undergo the surgery. *Id.* at ¶¶ 7–8.

Dr. Barrack performed Seals's total left-hip replacement in January 2010. *Id.* at ¶ 8. In August 2014, Dr. Barrack and Seals at least discussed the possibility of a revision surgery (a surgery to remove and replace the original implant) because of Seals's elevated metal-ion levels and increasing pain. *Id.* at ¶ 26. The parties disagree whether Dr. Barrack recommended a revision surgery at that time or whether Seals and Dr. Barrack agreed to take a wait-and-see approach. *Id.* Ultimately, in July 2020, Dr. Barrack performed a revision surgery. *Id.* at ¶¶ 27–28.

A hip joint has two main components, the ball and the socket; the ball is the spherical end of the femur bone, which inserts into the rounded bone structure of the pelvic bone, i.e. the socket. A hip implant consists of two main components, the head and the socket (consisting of a shell and liner), which mimic the corresponding bones. *See* Doc. 78 at ¶¶ 2, 5, 9; Doc. 67-2 at pp. 6–7. Wright Medical Technology, Inc. manufactured certain lines of hip-replacement components including the Dynasty, Conserve, and Profemur lines. *Id.* at ¶ 3. The Conserve head component and the Dynasty liner component implanted in Seals's 2010 surgery replace the natural hip joint. *Id.* at ¶ 5. Wright Medical made both the Conserve head component and Dynasty liner component from cobalt chromium metal alloys. *Id.* at ¶ 5. Thus, the Dynasty and Conserve products belong to the "metal-on-metal" category of hip prostheses, meaning the metal head inserts into, and rubs against, the metal socket. *Id.* at ¶¶ 4-5. The FDA cleared Seals's hip-replacement components for commercial distribution before Dr. Barrack implanted them into Seals. *Id.* at ¶ 10.

Dr. Barrack testified that at the time of Seals's initial hip-replacement surgery he (Dr. Barrack) was aware of risks associated with metal-on-metal hip implants, "such as release of metal ions, adverse local tissue reactions to metal, elevated ion levels, and pseudotumor reaction to metal components." Doc. 78 at ¶ 22; Doc. 67-5 at pp. 9:1–10:4, 22:9–24:1.[1]

II. Motions to exclude experts

A. Legal Standard

Federal law governs the admissibility of expert testimony in diversity cases. *Clark v. Heidrick*, 150 F.3d 912, 914 (8th Cir. 1998). In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, the United States Supreme Court interpreted the then-effective version of Rule 702 of the Federal Rules of Evidence to require district courts to be certain that expert evidence based on scientific, technical, or other specialized knowledge is "not only relevant, but reliable." 509 U.S. 579, 590 (1993). The district court must make a "preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue." *Id.* at 592–93.

Post-*Daubert* amendments to Rule 702 clarify the standard:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

[1] For ease of reference, the Court uses the page numbers from the CM/ECF header.

Fed. R. Evid. 702; *see also* Fed. R. Evid. 702 advisory committee's note to 2000 amendment ("Rule 702 has been amended in response to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, and to the many cases applying *Daubert* . . . ." (internal citation omitted)).

The Eighth Circuit has fleshed out the Rule 702 standards. Proposed expert testimony must meet three criteria to be admissible under Rule 702. "First, evidence based on scientific, technical, or other specialized knowledge must be useful to the finder of fact in deciding the ultimate issue of fact. This is the basic rule of relevancy." *Lauzon v. Senco Prods., Inc.*, 270 F.3d 681, 686 (8th Cir. 2001). "Second, the proposed witness must be qualified to assist the finder of fact." *Id.* (citation omitted). "Third, the proposed evidence must be reliable or trustworthy in an evidentiary sense, so that, if the finder of fact accepts it as true, it provides the assistance the finder of fact requires." *Id.* (internal quotation marks omitted). To meet the third criterion, the testimony must be "based on sufficient facts or data" and be "the product of reliable principles and methods," and the expert must have "reliably applied the principles and methods to the facts of the case." Fed. R. Evid. 702(b)–(d).

"Federal Rule of Evidence 702 reflects an attempt to liberalize the rules governing the admission of expert testimony." *Shuck v. CNH Am., LLC*, 498 F.3d 868, 874 (8th Cir. 2007) (citing *Lauzon*, 270 F.3d at 686). The rule "favors admissibility if the testimony will assist the trier of fact." *Clark*, 150 F.3d at 915. Doubt regarding "whether an expert's testimony will be useful should generally be resolved in favor of admissibility." *Id.* (citation and internal quotation omitted).

Under Rule 702, the trial court has gatekeeping responsibility to "ensur[e] that an expert's testimony both rests on a reliable foundation and is relevant to the task at hand." *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999) (citing *Daubert*, 509 U.S. at 597). "When

making the reliability and relevancy determinations, a district court may consider: (1) whether the theory or technique can be or has been tested; (2) whether the theory or technique has been subjected to peer review or publication; (3) whether the theory or technique has a known or potential error rate and standards controlling the technique's operation; and (4) whether the theory or technique is generally accepted in the scientific community." *Russell v. Whirlpool Corp.*, 702 F.3d 450, 456 (8th Cir. 2012) (citing *Daubert*, 509 U.S. at 593–94). "This evidentiary inquiry is meant to be flexible and fact specific, and a court should use, adapt, or reject *Daubert* factors as the particular case demands." *Unrein v. Timesavers, Inc.*, 394 F.3d 1008, 1011 (8th Cir. 2005). "There is no single requirement for admissibility as long as the proffer indicates that the expert evidence is reliable and relevant." *Id.*

As a general rule "the factual basis of an expert opinion goes to the credibility of the testimony, not the admissibility, and it is up to the opposing party to examine the factual basis for the opinion in cross-examination." *Nebraska Plastics, Inc. v. Holland Colors Americas, Inc.*, 408 F.3d 410, 416 (8th Cir. 2005) (quoting *Hartley v. Dillard's, Inc.*, 310 F.3d 1054, 1061 (8th Cir. 2002)). However, "if the expert's opinion is so fundamentally unsupported that it can offer no assistance to the jury, it must be excluded." *Id.* (citing *Hartley*, 310 F.3d at 1061). An expert opinion is fundamentally unsupported when it "fails to consider the relevant facts of the case." *Id.*

B. Dr. George Kantor

Seals's expert Dr. George S. Kantor, is a medical doctor and licensed orthopedic surgeon who, during his 35 years of practice, has performed more than 5,000 total-hip procedures, including many revision procedures. Doc. 75-1 at pp. 1–4; 28–34. He has been board certified since 1986 by the American Board of Orthopaedic Surgery.

1. Dr. Kantor's opinions

Seals retained Dr. Kantor as a medical and orthopedic-surgery expert. Doc. 75-1 at p. 5. In his report, Dr. Kantor "provide[d] fact and/or opinion testimony regarding the concept, development, design and performance of the [metal on metal] bearing surfaces, including those manufactured by Wright Medical, Inc." *Id.* He also "[gave] general opinions regarding damages and/or injuries that may occur due to metal on metal bearing surface failures and toxic metal ions generated by total hip arthroplasty systems," including "metal ions generated by biochemical and mechanical interactions from modular junctions." *Id.*

2. Wright Medical's motion to exclude

Wright Medical moves under Rule 702 to exclude Dr. Kantor's opinions that its Dynasty devices are defectively designed and the devices' Instructions for Use are inadequate, and his opinion regarding "metal toxicity."

a. Dr. Kantor's design-defect opinions

Wright Medical argues that Dr. Kantor's opinion that the Dynasty metal-on-metal devices are defectively designed "stem[s] from Dr. Kantor's overarching premise that all metal-on-metal devices are defectively designed." Doc. 63 at p. 10 (citing Doc. 63-2 at p. 19). Wright Medical asserts that "Dr. Kantor has not made any attempt to connect this overbroad conclusion to the facts of this particular case, or the specific design of the products at issue." *Id.* Wright Medical further argues that "Dr. Kantor has reviewed essentially nothing specific to the [Dynasty] devices at issue to substantiate" his opinion. *Id.*

Wright Medical attempts to make much of the fact that, in a multidistrict litigation, a court allowed Dr. Kantor to offer a general opinion that all metal-on-metal devices are defectively designed yet excluded Dr. Kantor's opinion about a particular implant. Doc. 63 at p.

11 (citing *In re Biomet M2a Magnum Hip Implant Prod. Liab. Litig.*, No. 3:12-MD-2391, 2017 WL 10845178, at *17 (N.D. Ind. Dec. 21, 2017)). However, Wright Medical does not identify what Dr. Kantor's device-specific opinions were in that case. *See id.* The Court notes that the Biomet MDL court stated that Dr. Kantor did not identify "how the [specific] products share the problems of other devices." *Id.* at *17. Here, Dr. Kantor proffers the opinion that Wright Medical's metal-on-metal devices are defectively designed because of their metal-on-metal articulation. Doc. 63-1 at p. 23.

In a Biomet hip-implant case remanded to this Court from the MDL, the undersigned found that Dr. Kantor's similar opinion regarding metal-on-metal implants satisfied the requirements of Fed. R. Evid. 702, and permitted his testimony. *See Bayes v. Biomet, Inc.*, No. 4:13-CV-00800-SRC, 2020 WL 5095346, at *8 (E.D. Mo. Aug. 28, 2020); *id.* at Doc. 314 (Kantor trial testimony). As in *Bayes*, the Court does not find Dr. Kantor's opinion "so fundamentally unsupported that it can offer no assistance to the jury." *Synergetics, Inc. v. Hurst*, 477 F.3d 949, 956 (8th Cir. 2007) (quoting *Bonner v. ISP Techs., Inc.*, 259 F.3d 924, 929–30 (8th Cir. 2001)).

b. Dr. Kantor's opinions regarding instructions for use

Wright Medical argues that Dr. Kantor's opinions regarding the warnings in the Instructions for Use at issue "are nothing more than *ipse dixit* and guesswork," because it claims he did not review the specific Instructions at issue. Doc. 63 at p. 15; Doc. 84 at p. 8. Seals responds that Dr. Kantor previously reviewed the Dynasty Instructions for Use, obviating the need to re-review them before his deposition in this case. Doc. 75 at p. 9.

When asked at deposition whether he had "reviewed documents specific to the Dynasty metal-on-metal product from Wright Medical," Dr. Kantor stated that he had, and further

explained that he had reviewed the "Instructions for Use, as well as surgical data provided to surgeons." Doc. 75-3 at p. 9:22–11:4. Dr. Kantor also explained what specific information he believed should have been included in the Instructions for Use in 2010. Doc 75-3 at pp. 21:25–26:23.

The Court agrees with Seals that any argument regarding when Dr. Kantor reviewed the Instructions for Use goes to weight rather than admissibility—and Wright Medical may certainly cross-examine Dr. Kantor on that basis. Wright Medical makes much of the fact that Dr. Kantor could not identify the specific Instruction for Use he was referring to, arguing that "there were different versions of Wright's [Instructions for Use], updated at different times, that accompanied the devices" implanted in Seals. Doc. 84 at p. 7. However, Wright Medical does not argue that the information Dr. Kantor stated was missing from the Instructions was actually in them, and the Court does not find Dr. Kantor's opinions regarding the instructions "so fundamentally unsupported that it can offer no assistance to the jury." *Synergetics*, 477 F.3d at 956 (quoting *Bonner*, 259 F.3d at 929–30); *see also In re Biomet*, 2017 WL 10845178, at *18 (concluding that Dr. Kantor's opinion regarding instructions for use was admissible because it compared facts in evidence with the content in the instructions).

Wright Medical also argues that Dr. Kantor's opinions regarding the Instructions are unhelpful to a jury because they merely re-assert his design-defect opinions. Doc. 63 at pp. 15–16. During Dr. Kantor's deposition, Wright Medical asked: "Are you basically saying it doesn't matter what [the Instructions for Use] say, unless it says don't use this product, the [Instructions for Use] are inadequate?" Doc. 63-2 at p. 26:16–20. Dr. Kantor answered: "The [Instruction for Use] is inadequate. The product is defective." *Id.* However, when asked to clarify why the instructions at the time of Seals's surgery were inadequate, Dr. Kantor explained that the

Instructions failed to warn about the danger posed by introducing—without clinical trials—second-generation metal-on-metal systems without fully understanding the failures of first-generation metal-on-metal systems. Doc. 63-2 at pp. 26:21–28:23.

As explained below, the Court grants Wright Medical's summary-judgment motion on Seals's failure-to-warn claim, but reserves ruling on Wright Medical's summary-judgment motion regarding punitive damages, an issue on which Dr. Kantor's explanation may be relevant. Accordingly, while the Court denies Wright Medical's motion to exclude Dr. Kantor's opinions regarding the Instructions for Use, the Court will not permit testimony from Dr. Kantor—or any other witness—regarding the adequacy of Wright Medical's Instructions for Use absent a showing of admissibility on some claim or defense still at issue. *See* Fed. R. Evid. 401.

c. Dr. Kantor's opinions regarding toxicity

Third, Dr. Kantor offers "general opinions regarding damages and/or injuries that may occur due to metal on metal bearing surface failures and toxic metal ions generated by total hip arthroplasty systems." Doc. 63-1 at p. 4. Wright Medical argues that the Court must exclude Dr. Kantor's opinions related to metal toxicity because "Dr. Kantor is not a toxicologist." Doc. 63 at p. 16. Wright Medical says that Dr. Kantor's lack of credentials in toxicology, combined with his statement that "[a] high school chemistry student would understand" that metal ions are toxic, shows that his metal-toxicity opinions are "not 'rooted in medical knowledge.'" *Id.* at p. 17 (quoting *Jones v. Lincoln Elec. Co.*, 188 F.3d 709, 723–24 (7th Cir. 1999)).

Wright Medical's arguments on this point misstate the record. Dr. Kantor did not simply offer the opinion that "[m]etal ions are toxic." Doc. 63 at p. 17. He discussed Seals's medical records and compared Seals's ion levels to "well accepted base line values." Doc. 75-1 at p. 24. He also relied on reports by Dr. Baker, a nuclear radiologist. *Id.* at p. 25.

Dr. Kantor is not a toxicologist, but that does not preclude him from testifying on the effects of metal toxicity on orthopedic systems. Rule 703 permits an expert to rely on facts and data that an expert in the particular field would reasonably rely upon, including the opinion of another expert. *See Nicholson v. Biomet, Inc.*, 46 F.4th 757, 765–66 (8th Cir. 2022) (holding that biomedical engineer properly relied on "medical experts' opinions" as contemplated by Rule 703 in concluding that the defendants' metal-on-metal hip implant was defectively designed); *Sosna v. Binnington*, 321 F.3d 742, 746 (8th Cir. 2003) (citing *Arkwright Mut. Ins. Co. v. Gwinner Oil, Inc.*, 125 F.3d 1176, 1182 (8th Cir. 1997)); *see also Dura Auto. Sys. of Indiana, Inc. v. CTS Corp.*, 285 F.3d 609, 613 (7th Cir. 2002) ("[I]t is common in technical fields for an expert to base an opinion in part on what a different expert believes on the basis of expert knowledge not possessed by the first expert."). *Cf.* Fed. R. Civ. P. 703 advisory committee's note to 1972 proposed rules and note to 2000 amendments. The Court finds that Dr. Kantor did so here.

The Court finds that Wright Medical's criticism of Dr. Kantor's toxicology opinions goes to weight, rather than admissibility. *Synergetics*, 477 F.3d at 955 (quoting *Bonner*, 259 F.3d at 929). Wright Medical may cross-examine Dr. Kantor regarding the factual basis for his opinion. In sum, the Court denies Wright Medical's motion to exclude Dr. Kantor's opinions.

C. Dr. Francis Gannon

Seals's expert Dr. Francis H. Gannon is a medical doctor who has practiced pathology for over 25 years. Doc. 61-3 at pp. 2–3. He is board certified in anatomic pathology, which involves the study of tissue in clinical medicine practice and research. Doc. 74 at p. 1 (citing Doc. 61-1 at p. 23:5–6).

1. Dr. Gannon's opinions

In his report, Dr. Gannon opined that Seals "experienced an adverse reaction to metal debris as a result of wear from metal to metal contact in the implanted hip components." Doc. 61-2 at p. 2. According to Dr. Gannon, "[t]his led to accumulation of metal wear debris in and around the implant site, causing subsequent tissue destruction, bone damage, pain and difficulty ambulating and eventually leading revision surgery." *Id.* Dr. Gannon also stated: "My opinions herein are to a reasonable degree of medical certainty and are based upon my education, training, clinical and practical experience, working knowledge of the published medical and scientific literature over the course of my career, and review and/or examination of medical records, reports and/or tissue specimens taken from the left hip revision surgery as well as other records provided to me." *Id.* His report contains several pages of technical discussion as well as a list of "[a]dditional bases and reasons for opinions, including additional supporting opinions." *Id.* at pp. 2–5.

2. Wright Medical's motion to exclude

Wright Medical moves under Rule 702 to exclude Dr. Gannon's opinions regarding metal toxicity, specifically two statements: (1) Dr. Gannon's statement regarding the "toxic nature of cobalt and chromium," Doc. 61-2 at pp. 4–5; and (2) Dr. Gannon's statement that "cobalt and chromium [wear] debris is also directly cytotoxic, meaning it will kill the cells in the area," Doc. 61-1 at p. 35:18–36:3.

Wright Medical argues that Dr. Gannon's opinions regarding the toxic nature of cobalt and chromium are out of the scope of Dr. Gannon's expertise as a pathologist, and that Dr. Gannon did not employ a reliable methodology in forming them. Doc. 61 at pp. 10–14. In response, Seals argues that Dr. Gannon "is a medical doctor who reviewed and relied on peer-

reviewed literature to support this proposition." Doc. 74 at p. 6 (citing Doc. 61-2 at p. 2). The Court agrees. Though—like Dr. Kantor—Dr. Gannon is not a toxicologist, that fact does not preclude him from testifying on the effects of metal toxicity on orthopedic systems. Rule 703 permits an expert to rely on fact and data that an expert in the particular field would reasonably rely upon, including the opinion of another expert. *See Nicholson*, 46 F.4th at 765–66; *Sosna*, 321 F.3d at 746 (citing *Arkwright Mut. Ins. Co.*, 125 F.3d at 1182); *see also Dura Auto.*, 285 F.3d at 613. *Cf.* Fed. R. Civ. P. 703 advisory committee's note to 1972 proposed rules and note to 2000 amendments. The Court finds that Dr. Gannon did so here.

The Court finds Wright Medical's criticism of Dr. Gannon's opinions goes to weight, rather than admissibility. *Bonner*, 259 F.3d at 929. Wright Medical may cross-examine Dr. Gannon regarding the factual basis for his opinion. However, the Court denies Wright Medical's motion to exclude Dr. Gannon's opinions at this "gatekeeping" stage.

D. Dr. Stephen Li

Seals's expert Dr. Stephen Li is a biomechanical engineer who holds a Ph.D. in chemistry and has testified before the FDA multiple times regarding metal-on-metal implants. Doc. 76-3 at pp. 2–3. Seals retained Dr. Li "as an expert in the fields of biomedical engineering, particularly regarding the materials, design, testing, and clinical results of hip implants." Doc. 76-2 at p. 2.

1. Dr. Li's opinions

In his report, Dr. Li summarized and provided the basis for his opinions, and stated that they were "within a reasonable degree of engineering and scientific certainty." Doc. 76-2 at p. 3. Dr. Li provided a twenty-nine-point summary of his opinions (and facts supporting those opinions). *Id.* at pp. 3–4. The Court includes some, but not all, of Dr. Li's twenty-nine summarized bullet points here. Dr. Li opined that Seals's Wright Medical hip-replacement

device "was defective in design and unreasonably dangerous because of the metal-on-metal articulation," and that "Wright Medical did not adequately warn of the dangers" of the device "due to the defective [metal-on-metal] design." *Id.* at p. 5. Dr. Li also provided an opinion on the issue of wear in hip replacements, explaining that "[i]n a [metal-on-metal] hip implant, there are two forms of wear, particulate debris and metal ions which cause severe adverse reactions that require revision surgery." Doc. 65-1 at pp. 10–15. Dr. Li also opined that Seals's "implant failed due to adverse reaction to the metal debris . . . and ions created by his [metal-on-metal] hip replacement." Doc. 65-1 at p. 4. Dr. Li stated that Seals's blood metal ion levels were "more than 20X normal," and that "[t]he clinical consequences of [adverse reaction to metal debris] suffered by Mr. Seals included pain, osteolysis (bone loss requiring bone graft), tissue necrosis, pseudotumor and effusion." *Id.*

2. Wright Medical's motion to exclude

Wright Medical moves under Rule 702 to exclude Dr. Li's opinion that its Dynasty hip-replacement devices are defectively designed; his opinions regarding metal wear and its relation to Seals's need for revision surgery; and his opinions regarding what Wright Medical characterizes as "medical causation" and "metal toxicity." The Court addresses each in turn.

a. Li's design-defect opinions

First, Wright Medical argues that Dr. Li's design-defect opinions are unreliable because they are "based on virtually no facts or data that actually relate to the design of the [Dynasty] devices." Doc. 65 at pp. 8–12. Wright Medical specifically seeks to exclude Li's opinion that "[t]he Wright Medical Conserve A Class Total Femoral [Metal-on-Metal] Hip Replacement was defective in design and unreasonably dangerous because of the metal-on-metal articulation." Doc. 65 at pp. 8–9. Wright Medical also objects to Dr. Li's opinion that its Dynasty devices

"produced increased metal wear compared to other available products," but does not identify the part of Dr. Li's report to which the latter refers. *See* Doc. 65 at pp. 8–9.

Wright Medical points to Dr. Li's admission that he did not review internal Wright Medical documents, such as design-development files or manufacturing records specific to the devices at issue in this case. Doc. 65 at p. 10. Wright Medical claims that the documents Dr. Li did review consisted of "extremely limited high-level summaries and marketing pieces available publicly," which Wright Medical claims "provide no specific design or manufacturing specifications at all." *Id.* "In short," Wright Medical argues that "Dr. Li reviewed essentially nothing specific to the [Dynasty] devices at issue in reaching his conclusion that they are defectively designed." *Id.* at p. 11. Wright Medical also argues that Dr. Li cannot overcome his failure to consider specific facts by "asserting that the [Dynasty] devices are defectively designed because all metal-on-metal devices are defectively designed," because "such a conclusion requires too great an analytical leap to survive a Rule 702 challenge." Doc. 65 at p. 11.

Wright Medical argues that the Court should adopt the reasoning from *In re: Biomet*, where the court allowed Dr. Kantor to testify regarding "design problems and risks associated with metal-on-metal devices generally," but excluded his device-specific opinions as unreliable, concluding that "the record doesn't demonstrate that Dr. Kantor considered sufficient data in developing his opinion on the risks associated with and the design defects of Biomet devices specifically . . . ." 2017 WL 10845178, *17.

In response, Seals argues that Dr. Li's opinion is that Wright Medical's device is defective "because of the metal-on-metal articulation." Doc. 76 at p. 6. And "by opining that all [metal-on-metal] devices are deficient," Seals argues that "Dr. Li necessarily offers that opinion

about [Wright Medical]'s device as well." *Id.* Seals claims that the following sections of Li's report provide "ample support" for this opinion:

- "Historical information about how [metal-on-metal] devices failed initially, and then were re-introduced into the market without sufficient testing" (citing Doc. 76-2 at p. 4, ¶¶ 7–12);
- "The FDA's decision that a [metal-on-metal] implant should never be a first-choice treatment, along with subsequent publications detailing the dangers associated with [metal-on-metal] implants" (citing Doc. 76-2 at p. 4, ¶¶ 14–16);
- "An explanation as to how the smaller particles of metal, as compared with polyethylene, create more lost particles, which in turn leads to osteolysis" (citing Doc. 76-2 at p. 5, ¶¶ 19–20); and
- "Information that metal connections are a source of metal ions and debris from corrosion and wear-related mechanisms." (citing Doc. 76-2 at p. 5, ¶ 23).

Doc. 76 at p. 6.

Seals adds that Dr. Li testified during his deposition that "the metal-on-poly [implant] has always been the best option for every patient. I can't think of a situation where another bearing surface would be preferred." Doc. 76 at p. 7 (quoting Doc. 76-1 at pp. 19:21–20:3). Seals also points out that in *Bayes v. Biomet*, the Court noted that the "[p]laintiffs' criticism of metal-on-metal hip implants is criticism of a particular design choice," and denied summary judgment for the defendant on the plaintiffs' failure-to-warn claim because "[w]hether metal-on-metal articulation in hip implants is always unreasonably dangerous is a disputed question of fact." 2020 WL 5095346, at *12.

The Court agrees with Seals that Dr. Li provided sufficient support for his design-defect opinions. And in opining that Wright Medical's device, like all metal-on-metal devices, is defective "because of the metal-on-metal articulation," Doc. 76 at p. 6, the Court finds that Dr. Li did not "fail[] to take into account a plethora of specific facts"; thus, his design-defect opinions are not "so fundamentally unsupported that [they] can offer no assistance to the jury."

Nebraska Plastics, 408 F.3d at 416–17. Accordingly, the Court denies Wright Medical's motion to exclude Dr. Li's design-defect opinions.

b. Dr. Li's opinions regarding metal wear

Second, Wright Medical argues that Dr. Li's design-defect opinions regarding metal wear at pages 22–27 of his report (Doc. 65-1 at pp. 10–15) are the product of unreliable methodology and "lack fit with this case." Doc. 65 at pp. 12–16.

Wright Medical argues that Dr. Li's opinions regarding metal wear are unreliable because they are based on a "series of assumptions" and "are not appropriately tied to the facts of this case." Doc. 65 at p. 14–16. Seals responds by arguing that at pages 22–27 of his report "Dr. Li does not purport to be identifying a precise amount of wear that will occur in a [metal-on-metal] implant; he is simply making the case that [metal-on-metal] devices release substantially more particles due to wear than polyethylene devices, which, in turn makes them more dangerous." Doc. 76 at p. 10 (citing Doc. 76-2 at pp. 23–28).

The Court notes that Wright Medical does not move to exclude other sections of Dr. Li's report regarding his observation of the wear in Seals's retrieved device components, or Dr. Li's opinion that the "retrieved components exhibited signs of metal wear and corrosion that are consistent with the presence of [adverse reaction to metal debris]." Doc. 76-2 at p. 5, ¶ 26; *see also id.* at p. 50 ("The amount of wear was typical for a metal-on-metal hip replacement and represents the significant amount of metal wear that occurs.").

The Court agrees that Dr. Li's opinions at pages 22–27 of his report (Doc. 76-2 at pp. 23–28) regarding the wear rate of metal-on-metal implants is relevant to his "using any metal-on-metal hip replacement is really a terrible idea" opinion. Doc. 76 at p. 7. Further, the opinions are not merely based on a "series of assumptions," as Wright Medical claims. Doc. 65 at p. 14.

Rather, the Court agrees with Seals that Dr. Li provides sufficient support from scientific literature for his wear-rate opinions. *See* Doc. 76 at p. 10 (citing Doc. 76-2 at pp. 23–28). Wright Medical may cross-examine Dr. Li regarding the factual basis of these opinions, but the Court denies Wright Medical's motion to exclude them as irrelevant or unreliable. *See Nebraska Plastics*, 408 F.3d at 416.

c. Dr. Li's opinions regarding medical causation and toxicology

Third, Wright Medical argues that the Court should exclude Dr. Li's opinions on medical causation and the effects of metal ions in the body, because those opinions are outside his area of specialized knowledge. Doc. 65 at pp. 17–19. Wright Medical specifically identifies two medical-causation opinions in Li's report: (1) "Mr. Seals [sic] implant failed due to adverse reaction to the metal debris (ARMD) and ions created by his [metal-on-metal] hip replacement"; and (2) "in just over 2 years from receiving his hip replacement [Seals] began to experience complications due to production of metal debris and ions from the implants." Doc. 65-1 at pp. 4, 21. Seals concedes that Dr. Li "does not have the expertise to give medical causation opinions" and "will not testify about the clinical impacts of the device on Mr. Seals." Doc. 76 at pp. 12–13. Accordingly, the Court will not permit Dr. Li to opine on the medical causation of Seals's injuries. *See Bayes v. Biomet, Inc.*, No. 4:13-CV-00800-SRC, 2020 WL 5594059, at *6 (E.D. Mo. Sept. 18, 2020) (citations omitted) (granting motion to preclude biomechanical-engineering expert from opining on medical causation).

As to "metal toxicity," Wright Medical argues that, given Dr. Li's "lack of specialized knowledge to offer opinions on issues of toxicology," the Court should exclude Dr. Li's "opinions on purported effects of metal particles and metal ions in the body stemming from the

wear of metal-on-metal devices like those at issue, and the effects of those ions in Plaintiff specifically." Doc. 65 at pp. 17–19 (citing Doc. 65-1 at pp. 4, 11, 16).

Among other arguments, Seals relies on *In re Biomet*, where the court allowed Dr. Truman, plaintiffs' biomedical expert, to opine that metal-on-metal devices can cause "elevated metal ions with immune response complications . . . and tissue necrosis." 2017 WL 10845178, at *14. Citing Rule 703, the court concluded that "[Dr.] Truman can't testify as an expert on the clinical effects of metal ions, but she can permissibly rely on other experts' opinions that metal ions cause clinical effects to support her opinion that metal-on-metal devices are unreasonably dangerous." *Id.* at *15. Seals urges the Court to reach the same conclusion here. Doc. 76 at p. 14.

The Court agrees with Wright Medical that *In re Biomet* does not "stand for the conclusion that the engineering expert herself could provide her own, independent opinions on the plaintiff's actual condition resulting from such devices . . . ." Doc. 85 at pp. 14–15. Dr. Li may not offer his own independent opinions regarding the clinical effects of metal particles or ions. But as in *In re Biomet*, 2017 WL 10845178, at *14, Dr. Li's report shows that the opinions at issue support one of his "central conclusions"—that "using any metal-on-metal hip replacement is really a terrible idea . . . ." Doc. 76-1 at p. 18:3–8. And in his report, Dr. Li includes numerous footnotes detailing the literature he relied on. See Doc. 76-2 at pp. 9–31. Dr. Li may rely on those opinions under Rule 703 to support his opinions regarding the risks of metal-on-metal devices generally, but other limitations apply.

In addition to permitting Dr. Li to "explain why [metal-on-metal] devices present a risk to patients generally," Seals argues that the Court should allow Dr. Li to "cite Mr. Seals's medical records to the extent that the information therein supports his larger opinions . . . ." Doc.

76 at p. 15. For example, Seals argues that while "it will be up to a medical expert to explain the ways in which elevated cobalt levels put Mr. Seals's health at risk," the Court should allow Dr. Li to "discuss the extremely high levels of cobalt in Mr. Seals's body, as evidence that corrosion from the device affected him." Doc. 76 at p. 13; *see also id.* at p. 14 ("In addition to opining about the general effects of [metal-on-metal] implants, Dr. Li should be permitted to discuss any details from Dr. Seals's [sic] presentation that support his opinions. One important example would that Mr. Seals had 20 times the typical level of cobalt in his blood before his revision surgery—a sign of the presence of metal ions from the device." (citing Doc. 76-2 at p. 29)).

Seals again cites *In re Biomet*, where the court allowed Dr. Truman to opine—based on other experts' opinions—that metal ions cause "immune response complications . . . and tissue necrosis." Doc. 76 at p. 14 (citing *In re Biomet*, 2017 WL 10845178, at *14). But that holding does not support Seals's argument regarding Dr. Li's Seals-specific opinions above. The Court finds that these opinions stray into the realm of medical causation, and as already stated, the Court limits Dr. Li's testimony to the risks of metal-on-metal devices generally and will not permit Dr. Li to opine regarding the medical causation of Seals's injuries. In sum, the Court denies Wright Medical's motion to exclude Dr. Li's opinions, except as to medical causation.

E. Dr. Lawrence Eiselstein

Wright Medical retained Dr. Lawrence Eiselstein as an expert in materials science. Doc. 73 at p. 4. Eiselstein is a metallurgist and engineer with more than 30 years of experience in the field of "design and failure analysis." Doc. 73-2 at p. 4. He received a Ph.D. in materials science from Stanford University in 1983 and is licensed as a Professional Engineer in California in the fields of metallurgical engineering and corrosion engineering. *Id.* at p. 4. His research includes "the mechanical behavior of materials (strength, fracture, fatigue, wear, and creep),

armor development, corrosion science, and testing as applied to material selection, coating evaluation, breakdown potential, repassivation, polarization, galvanic, stress corrosion cracking (SCC), and hydrogen embrittlement issues." *Id.*

1. Dr. Eiselstein's opinions

After receiving Seals's explanted (i.e. removed during revision surgery) hip-replacement components, Dr. Eiselstein visually inspected the components and conducted "photo-documentation, optical microscopy, scanning electron microscopy (SEM) and electron dispersive spectroscopy (EDS)" analysis. Doc. 73-2 at p. 5. Dr. Eiselstein opined that: (1) the materials Wright Medical used in the components were "widely accepted as implantable and were appropriate for this application"; (2) "the products implanted in Mr. Seals were not defective or defectively designed"; and (3) "Biological material" found in Seals's "femoral head taper" was "consistent with possible biological contamination," which "can lead to suboptimal assembly of the implant and can negatively affect performance." *Id.* at p. 11. In other words, Dr. Eiselstein opined that Wright Medical properly designed and manufactured the implant, and that contamination may have occurred due to improper implant assembly during the implant surgery, which may account for the problems Seals experienced. *Id.* at pp. 12–13. Additionally, Dr. Eiselstein commented on Dr. Li and Dr. Kantor's opinions. *Id.* at pp. 11–13.

2. Seals's motion to exclude

Seals moves under Rule 702 to exclude Dr. Eiselstein's opinions regarding possible contamination as an alternative explanation for device failure, arguing that Dr. Eiselstein's opinions are unreliable and would be confusing to a jury. Doc. 59 at pp. 2–4. The Court addresses these two arguments in turn.

First, Seals argues that Dr. Eiselstein's use of "possible," "could have," and "may have" means his opinions regarding potential contamination as an alternative explanation for device failure "are not issued with any degree of scientific certainty." Doc. 59 at p. 3. Similarly, Seals argues that the opinions are unreliable because Dr. Eiselstein "does not offer evidence from which he can opine whether the contamination existed at the time of implant or whether the contamination occurred after the device components were removed from Mr. Seals." Doc. 59 at p. 3 (citing *Barrett v. Rhodia, Inc.*, 606 F.3d 975, 981 (8th Cir. 2010)).

In *Barrett*, the Eighth Circuit affirmed the district court's exclusion of expert testimony where the expert conceded that "she lack[ed] significant scientific knowledge underpinning [her] opinion" and "did not rule out alternative causes of [the plaintiff's] injury prior to forming her opinion." 606 F.3d at 981. Noting that the expert's testimony "was admittedly based on assumption, without any scientific testing," the Eighth Circuit stated that "[e]xpert testimony is inadmissible where, as here, it is excessively speculative or unsupported by sufficient facts." *Id.*

Wright Medical responds that because Seals has the burden of proof, Wright Medical need only convince the jury that the alleged defect did not cause Seals's injuries. Doc. 73 at p. 11–12. Wright Medical points out that Seals's experts opine that the metal-on-metal interaction between the femoral head and acetabular liner was the source of metal ions in Seals's body, and that Dr. Eiselstein merely provides an additional or alternate explanation for the source of the ions. *Id.* at p. 11.

Wright Medical cites *Allen v. Brown Clinic, P.L.L.P*, where the Eighth Circuit rejected the argument that an expert in a medical malpractice case "should have been required to opine as to an alternative 'proximate' cause, not alternative 'possible' causes." 531 F.3d 568, 574 (8th Cir. 2008). The Eighth Circuit noted that adopting such a rule would preclude a defendant's

expert from testifying "unless he could conclusively state what proximately caused the injury," which "would impermissibly shift the burden of proof and require a defendant to 'disprove' a plaintiff's theory by a preponderance of the evidence." *Id.* Wright Medical accordingly argues that "Dr. Eiselstein's use of the words 'possible,' 'could have,' and 'may have,' in his opinion identifying a potential additional or alternative source of Plaintiff's metal ion levels does not provide sufficient grounds to exclude his testimony . . . ." Doc. 73 at p. 12. The Court agrees.

Second, Seals argues that Dr. Eiselstein's opinions "will confuse a jury because Wright Medical offers no medical expert testimony or evidence that the implanting surgeon, Dr. Barrack, breached the standard of care during the implant surgery." Doc. 59 at p. 3. According to Seals, before Wright Medical can argue the device failed due to contamination during surgery, it must offer "expert testimony that the implanting surgeon breached the standard of care by implanting a contaminated device." Doc. 59 at p. 3.

Seals relies on *Smith v. Tenet Healthsystem SL, Inc.*, where the Eighth Circuit held that the district court properly granted judgment as a matter of law for the defendant in a medical-malpractice case, because the plaintiff failed to offer expert testimony regarding causation. 436 F.3d 879, 888 (8th Cir. 2006)). The Eighth Circuit noted that "[o]ne of the elements of a medical malpractice claim is causation," and that "when a party suffers a sophisticated injury . . . expert testimony is required" to establish causation. *Id.*

The Court finds that *Smith* simply does not support Seals's argument that a defendant in a defective-medical-device case must offer expert testimony that the implanting physician breached the standard of care before the defendant can introduce evidence regarding other potential sources of contamination or device failure. The Court agrees with Wright Medical that Dr. Eiselstein's testimony about elements observed in the femoral head taper of the retrieved

device is relevant and helpful to a jury because it tends to show an alternative source of Seals's elevated metal-ion levels. Doc. 73 at p. 2. The Court finds that Seals's criticism of Dr. Eiselstein's opinions go to weight, rather than admissibility. Accordingly, the Court denies Seals's motion to exclude Dr. Eiselstein's opinions.

F. Dr. Steven Kurtz

Wright Medical's expert Dr. Steven Kurtz has been a biomechanical engineer for more than twenty years, and holds a Ph.D. in Mechanical Engineering from Cornell University. Doc. 73-1 at p. 38. He is also a part-time research professor and Director of the Implant Research Center at Drexel University's School of Biomedical Engineering, Science, and Health Systems, where he supervises a hip- and knee-implant retrieval program. Doc. 73-1 at pp. 6, 28.

1. Dr. Kurtz's opinions

Dr. Kurtz opines that the use of an alternative metal-on-polyethylene or ceramic-on-polyethylene implant, with a smaller head size, would have increased the risk of dislocation compared to Seals's metal-on-metal implant. Doc. 59-3 at p. 2. Dr. Kurtz also opines that "[b]ased on the clinical and patient factors in this case, there is insufficient evidence that use of an alternative bearing would have averted [Plaintiff's] need for revision surgery." *Id.*

2. Seals's motion to exclude

Seals moves under Rule 702 to exclude Dr. Kurtz's increased-risk-of-dislocation opinion, arguing that it is "speculative and not adequately supported by reliable evidence." Doc. 59 at p. 5. The Court disagrees. In his report, Dr. Kurtz provided ample explanation, supported by literature, for his opinion that the use of a smaller head increases the risk of dislocation. Doc. 73-1 at pp. 26–27. Essentially, Dr. Kurtz explains that because dislocation in this type of device

requires a combination of force and displacement, increasing the distance the femoral head has to "jump" to dislocate increases stability and decreases dislocation risk. *Id.*

Seals also argues that Dr. Kurtz's opinion "defies reality" because no evidence exists that Seals has experienced dislocations since he received a ceramic-on-polyethylene replacement implant in 2020. Doc. 59 at p. 5. But while a lack of displacement since Seals's revision surgery may provide a basis for cross-examination, it does not render Dr. Kurtz's increased-risk-of-dislocation opinion inadmissible. *See Sphere Drake Ins. PLC v. Trisko*, 226 F.3d 951, 955 (8th Cir. 2000) ("Attacks on the foundation for an expert's opinion . . . go to the weight rather than the admissibility of the expert's testimony.").

The Court also notes that in his reply, Seals argues for the first time that Dr. Kurtz "cannot opine that a dislocation would even necessarily lead to hip revision surgery," because "[Dr.] Kurtz is not a medical doctor." Doc. 81 at pp. 1–2. As Seals did not raise this argument in his opening brief, Seals waived it. *See Chay-Velasquez v. Ashcroft*, 367 F.3d 751, 756 (8th Cir. 2004).

In sum, as the Court noted when considering a similar challenge to Dr. Kurtz's opinions in *Bayes v. Biomet, Inc.*, "[u]nder established Missouri law, a defendant in a design-defect case "[is] entitled to present evidence . . . of the relative safety of alternative designs." No. 4:13-CV-00800-SRC, 2020 WL 5594058, at *10 (E.D. Mo. Sept. 18, 2020) (quoting *Moore v. Ford Motor Co.*, 332 S.W.3d 749, 768 (Mo. 2011)). Dr. Kurtz has done so here. Thus, the Court denies Seals's motion to exclude Dr. Kurtz's opinions. Having addressed the parties' respective Rule 702 motions, the Court turns to Wright Medical's summary-judgment motion.

III. Wright Medical's motion for summary judgment

Seals's eight-count Complaint asserts claims against Wright Medical for failure to warn, design defects, manufacturing defects, breach of warranties, intentional misrepresentation, negligence, unfair trade practices, and punitive damages. The Court previously dismissed Seals's breach-of-warranties, intentional-misrepresentation, and unfair-trade-practices claims (counts 4, 5, and 7, respectively). Doc. 30. Wright Medical now moves for summary judgment on all remaining counts of Seals's Complaint.

A. Legal standard

Rule 56(a) of the Federal Rules of Civil Procedure provides that "[t]he court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." In ruling on a motion for summary judgment, the Court is required to view the evidence in the light most favorable to the non-moving party and must give that party the benefit of all reasonable inferences to be drawn from the underlying facts. *AgriStor Leasing v. Farrow*, 826 F.2d 732, 734 (8th Cir. 1987). The moving party bears the initial burden of showing both the absence of a genuine issue of material fact and entitlement to judgment as a matter of law. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 (1986); Fed. R. Civ. P. 56(a).

In response to the proponent's showing, the opponent's burden is to "come forward with 'specific facts showing that there is a genuine issue for trial.'" *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (quoting Fed. R. Civ. P. 56(e)). Self-serving, conclusory statements without support are insufficient to defeat summary judgment. *Armour and Co., Inc. v. Inver Grove Heights*, 2 F.3d 276, 279 (8th Cir. 1993). Rule 56(c) "mandates the entry of summary judgment, after adequate time for discovery and upon motion, against a party

who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

B. Discussion

1. Failure to warn (count 1)

Seals's surgeries occurred in Missouri, and the parties agree that Missouri law applies to the substantive claims in this case. *See* Doc. 68 at p. 8; Doc. 77 at p. 2. In Missouri, the elements of a cause of action for strict-liability failure to warn are: "(1) the defendant sold the product in question in the course of its business; (2) the product was unreasonably dangerous at the time of sale when used as reasonably anticipated without knowledge of its characteristics; (3) the defendant did not give adequate warning of the danger; (4) the product was used in a reasonably anticipated manner; and (5) the plaintiff was damaged as a direct result of the product being sold without an adequate warning." *Moore v. Ford Motor Co.*, 332 S.W.3d 749, 756 (Mo. 2011). Causation in a failure-to-warn case requires that the product with the missing warning cause the plaintiff's injuries and that a warning would have altered the behavior of the user of the product. *Arnold v. Ingersoll-Rand Co.*, 834 S.W.2d 192, 194 (Mo. 1992). A rebuttable presumption applies that "a warning, if provided, will be read and heeded." *Johnson v. Medtronic, Inc.*, 365 S.W.3d 226, 232 (Mo. Ct. App. 2012); *Grady v. Am. Optical Corp.*, 702 S.W.2d 911, 918 (Mo. Ct. App. 1985).

In his complaint, Seals claims that Wright Medical owed a duty to warn "all persons whom [Wright Medical] should have reasonably foreseen may use or be affected by the product, including, but not limited to, [Seals], [Seals]'s healthcare providers, and the FDA." Doc. 1 at ¶ 89. Wright Medical seeks summary judgment on Seals's failure-to-warn claim. First, Wright

Medical contends that, under the learned-intermediary doctrine, it had no duty to warn Seals personally or the Food and Drug Administration of the risks associated with its products. Second, Wright Medical argues that Seals cannot establish causation because Dr. Barrack had knowledge about the specific risks about which Seals alleges Wright Medical failed to warn.

The Court agrees that, as relevant to Seals's failure-to-warn claim, Wright Medical had no duty to warn Seals directly—or the Food and Drug Administration—of the risks associated with its products. Missouri courts apply the learned-intermediary doctrine in medical-equipment or medical-device cases involving failure-to-warn claims. *Doe v. Alpha Therapeutic Corp.*, 3 S.W.3d 404, 419 (Mo. Ct. App. 1999); *Kirsch v. Picker Int'l, Inc.*, 753 F.2d 670, 671 (8th Cir. 1985) ("Missouri law is clear [regarding the learned intermediary doctrine] with respect to prescription drugs, and these principles apply to x-ray equipment that can be utilized only at the direction of a physician." (citation omitted)). Under this doctrine, "a manufacturer of prescription drugs or products discharges its duty to warn by providing the physician with information about risks associated with those products." *Doe*, 3 S.W.3d at 419. "[A]ny warning given to the physician is deemed a warning to the patient." *Id.* "Thus, [Wright Medical] ha[d] a duty to properly warn only the doctor of the dangers associated with [its products]." *Kirsch*, 753 F.2d at 671.

The remainder of Seals's failure-to-warn claim rests on his allegation that Wright Medical failed to warn Dr. Barrack of certain risks. Wright Medical argues that Seals cannot show causation regarding any failure to warn Dr. Barrack because Dr. Barrack knew of the risks associated with metal-on-metal devices at the time of Seals's initial hip-replacement surgery, implanted the device with knowledge of those risks, and warned Seals of the risks that Seals now alleges materialized and resulted in a revision surgery. Doc. 68 at pp. 16–18.

In support, Wright Medical cites *Kirsch*, 753 F.2d 670. In *Kirsch*, the plaintiff alleged that x-ray treatments using the defendant's x-ray machines caused skin cancer. *Id.* at 670. The Eighth Circuit affirmed a directed verdict in the defendant's favor on the failure-to-warn claim, noting that the record contained considerable evidence that the treating physician knew of the cancer risks associated with radiation treatment. *Id.* at 672. In light of that evidence, the Eighth Circuit held that there was "simply . . . no evidence that [the treating physician] did not know of the danger in using radiation therapy." *Id.* at 672. Thus, "[a]ny failure to warn by [the manufacturer] could not have been the proximate cause of [the plaintiff]'s injuries." *Id.*

Wright Medical argues that here, as in *Kirsch*, Dr. Barrack was "fully aware" of the specific risks Seals alleges Wright Medical failed to warn about—the risks of metal reactions, "pseudotumors," and adverse tissue reactions—and that Dr. Barrack "made a specific decision, in his medical judgment, to recommend the Wright Medical devices after weighing the relevant risks and potential complications." Doc. 68 at p. 18.

Seals does not dispute that Dr. Barrack testified that in 2010 he was aware of risks associated with metal-on-metal hip implants, "such as release of metal ions, adverse local tissue reactions to metal, elevated ion levels, and pseudotumor reaction to metal components." Doc. 78 at ¶ 22; Doc. 67-5 at pp. 9:1–10:4, 22:9–24:1. And Seals does not suggest that the procedural posture of *Kirsch*—where the Eighth Circuit reviewed a directed verdict for the defendant on a failure-to-warn claim—renders that case inapplicable to Wright Medical's summary-judgment motion here. *See Anderson*, 477 U.S. at 250–51, 252 (observing that the summary-judgment standard under Fed. R. Civ. P. 56 "mirrors" the directed-verdict standard under Fed. R. Civ. P. 50(a), and that the difference is primarily procedural (citation omitted)).

Rather, Seals argues that *Kirsch* is inapposite because—according to Seals—Dr. Barrack testified that he was not aware of "(1) the *degree* of risk associated with metal-on-metal hip devices" or (2) the increased risk of carcinogenesis (formation of cancer) as a result of "metal releases from metal-on-metal hip devices." Doc. 77 at p. 8 (emphasis added). The Court addresses these two arguments in turn.

First, Seals claims that Dr. Barrack was not aware of the degree of risk "because he now concedes that metal-on-metal hip devices are no longer used because revision rates and metal ion releases are too high, and the risks outweigh the benefits." Doc. 78 at ¶ 22 (citing Doc. 78-7 at pp. 25:22–26:13; 28:11–20). Wright Medical argues that this testimony does not provide "evidence that Dr. Barrack was not aware of the degree of risks," because Dr. Barrack's testimony that he no longer uses metal-on-metal devices is not evidence that he would have made a different decision in 2010—particularly where he "testified that the evolution of new technology has changed the risk/benefit calculations over time." Doc. 82 at p. 5 (citing Doc. 78-7 at p. 33:8–15). The Court agrees.

Second, Seals claims that Wright Medical did not warn Dr. Barrack of the increased cancer risk associated with "metal releases" from metal-on-metal hip devices. Doc. 78 at ¶ 22 (citing Doc. 78-19). And, during Dr. Barrack's deposition, he answered "Yes" when asked: "If there were clinical data or risk analysis done by Wright Medical regarding their metal-on-metal hips that had determined a risk of [cancer] from the metal, is that something you would have liked to have known before this surgery?" Doc. 67-5 at pp. 46:19–47:20.

However, as Wright Medical notes, Dr. Barrack went on to testify that "you know, you have to put that in context," and "[i]t would only be relevant if it were any different than any other device." Doc. 83 at ¶ 49 (quoting Doc. 67-5 at pp. 46:19–47:20). Dr. Barrack continued:

"So if you're saying that there was an additional risk for this one device that was not present in other metal-on-metal devices, I would like to know it. I would be surprised if the FDA would allow it on the market if it were substantially different. But yes, if their device was uniquely risky, more so than the other devices I was using, I would like to know it, yes." Doc. 67-5 at p. 47:14–20. However, the evidence Seals puts forward regarding cancer risk—a "risk analysis" of the Wright Medical "Transcend" metal-on-metal device—does not provide the kind of device-specific evidence that Dr. Barrack testified he would have wanted to see. *See* Doc. 78-15 at pp. 2–9.

The Court also agrees with Wright Medical that in any event, because Seals has not provided evidence that he has been diagnosed with cancer or has a heightened risk of cancer in the future, Dr. Barrack's awareness of that risk is not material to this case. *See* Doc. 82 at pp. 4–5 (quoting *Campbell v. Am. Crane Corp.*, 60 F.3d 1329, 1332 (8th Cir. 1995) ("[O]ne cannot be liable for failing to warn of a danger which has not been encountered."). Thus, both of Seals's attempts to differentiate this case from *Kirsch* fail.

Seals also argues that a dispute of material fact exists regarding whether Dr. Barrack warned Seals of all the injuries Seals has suffered. Doc. 77 at p. 9. For example, Seals denies that Dr. Barrack gave him the warnings at the time of Seals's metal-on-metal implant surgery. Doc. 78 at ¶ 25. Seals also argues that "Dr. Barrack also testified that he does not remember Mr. Seals' surgery, so it is unlikely he can remember the warnings he provided to plaintiff." Doc. 78 at ¶ 25. But viewed in a light most favorable to Seals, all this shows is that Dr. Barrack may not have warned Seals—which is not the same as showing that Dr. Barrack was unaware of the risks. *See Kirsch*, 753 F.2d at 672 (under Missouri law, "a warning to the doctor is deemed a warning to the patient" (citing *Johnston v. Upjohn Co.*, 442 S.W.2d 93, 95 (Mo. Ct. App. 1969)); *Doe*, 3

S.W.3d at 419 (same). In sum, because Dr. Barrack testified that he was already aware of the risks of Wright Medical's metal-on-metal devices, the remainder of Seals's failure-to-warn claim fails as a matter of law. *See id*. at 71–72. Accordingly, the Court grants Wright Medical's motion for summary judgment as to count 1.

2. Design defect (count 2)

Having moved to exclude the testimony of Seals's two design-defect experts, Wright Medical moves for summary judgment on Seals's design-defect claim "[b]ecause Plaintiff cannot offer any admissible expert opinion to identify a defect in the design of the devices at issue." Doc. 68 at p. 21. In other words, Wright Medical's motion for stands or falls on the motions to exclude the testimony of Drs. Kantor and Li. Because the Court denies the relevant portions of those motions, the Court likewise denies the motion for summary judgment as to Seals's count 2.

3. Manufacturing defect (count 3)

Wright Medical moves for summary judgment on Seals's manufacturing-defect claim (count 3), arguing that Seals has presented no evidence of a manufacturing defect. Doc. 68 at pp. 22–23. Seals does not oppose Wright Medical's motion for summary judgment on this claim. Doc. 77 at p. 1. Accordingly, the Court grants the motion as to count 3.

4. Negligence (count 6)

In count 6, Seals alleges that Wright Medical was negligent in the "design, testing, distribution, manufacture, advertising, sale and marketing of the Conserve." Doc. 1 at ¶ 149. Wright Medical argues that Seals's claim for negligent manufacture fails for the same reason as his strict-liability manufacturing-defect claim and argues that Seal's claims of negligent distributing, advertising, sale, and marketing fail as well. Doc. 68 at pp. 23–24 & n.4. Seals does not oppose summary judgment on his claims of negligent manufacture, distribution,

advertising, sale, and marketing. Doc. 77 at p. 1. Accordingly, the Court grants summary judgment for Wright Medical on count 6 to the extent Seals alleged negligent manufacture, distribution, advertising, sale, and marketing.

Seals opposes Wright Medical's motion on count 6 as to his claims for negligent design, negligent failure to warn, and negligent testing. *Id.* Regarding Seals's claims of negligent design and negligent failure to warn, Wright Medical does not offer any argument for summary judgment on these claims separate from its arguments pertaining to strict-liability design defect and failure to warn. Presupposing that Seals's strict-liability claims fail as a matter of law, Wright Medical believes itself entitled to summary judgment on the related negligence claims. Doc. 68 at p. 24.

All of these claims—strict-liability design defect, negligent design, strict-liability failure to warn, and negligent failure to warn—share the same causation elements. *See Moore*, 332 S.W.3d at 764; *Peters v. Gen. Motors Corp.*, 200 S.W.3d 1, 21 (Mo. Ct. App. 2006). Because the Court denies Wright Medical's motion for summary judgment on Seals's strict-liability design-defect claim, the Court likewise denies Wright Medical's motion for summary judgment on the related negligent-design claim. And because the Court grants Wright Medical's motion for summary judgment on Seals's strict-liability failure-to-warn claim, the Court also grants Wright Medical's motion for summary judgment on the related negligent failure-to-warn claim.

Wright Medical also moves for summary judgment on Seals's negligent failure-to-test claim, arguing that Missouri law requires a defect in the product to support a negligent failure-to-test claim. Doc. 82 at pp. 9–11. Presupposing that Court will exclude the testimony of Drs. Kantor and Li, Wright Medical believes that Seals "cannot establish a defect in the devices at issue." *Id.* at p. 10. However, having denied the motions to exclude the relevant testimony, the

Court rejects this argument. Moreover, a dispute of material fact exists regarding whether Wright Medical adequately tested its products. *See* Doc. 78-4 at pp. 14–15 (Dr. Li opining that Wright Medical brought "its Conserve A-class metal-on-metal hip implants to market without adequate testing for known dangers."). The Court thus denies Wright Medical's motion for summary judgment on Seals's negligent-testing claim.

5. Punitive damages (count 8)

Wright Medical moves for summary judgment on Seals's claim for punitive damages (count 8). Doc. 68 at p. 24. Seals opposes the motion. The parties disagree whether Tennessee or Missouri law applies to the punitive-damages claim. *See* Doc. 68 at pp. 25–28 (arguing Tennessee law applies); Doc. 77 at pp. 10–11 (arguing Missouri law applies). The Court will address Wright Medical's motion for summary judgment as to count 8 separately. The Court advises the parties that it may, as it did in *Bayes*, bifurcate the issue of punitive damages.

IV. Conclusion

To the extent set out in this order, the Court grants in part and denies in part Wright Medical's [66] Motion for Summary Judgment, except as to count 8, which the Court will address separately. The Court grants in part and denies in part Wright Medical's [60] [62] [64] motions to exclude expert testimony. The Court denies Seals's [59] motion to exclude expert testimony.

So Ordered this 7th day of October 2022.

STEPHEN R. CLARK
UNITED STATES DISTRICT JUDGE